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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte LUKE ALPHEY and DEAN THOMAS

Appeal 2015-000048
Application 11/733,737
Technology Center 1600

Before CHRISTOPHER G. PAULRAJ, TAWEN CHANG and
DEVON ZASTROW NEWMAN, *Administrative Patent Judges*.

NEWMAN, *Administrative Patent Judge*.

DECISION ON REHEARING

This is a request for rehearing under 37 C.F.R. § 41.52 (“Req. Reh’g.”) of the decision on Appeal (“Decision”), entered February 2, 2017, in the above-identified application. In the Decision, we: (1) affirmed the rejection of claims 50–54 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 18, and 25–31 of U.S. Patent No. 7,998,475; (2) affirmed the Examiner’s the rejection of claims 38–44, 48–55, 61–69, 71–73, 75–83, and 87–91 under 35 U.S.C. §

103(a) as obvious over Fryxell,¹ Bello,² and Hammock;³ (3) affirmed the Examiner's the rejection of claim 57 under 35 U.S.C. § 103(a) as obvious over Fryxell, Bello, Hammock, and Namciu;⁴ and (4) affirmed the Examiner's the rejection of claim 59 under 35 U.S.C. § 103(a) as obvious over Fryxell, Bello, Hammock, and Deng.⁵ Decision 17. Appellants have requested rehearing of our Decision in its entirety.

We have granted Appellants' request to the extent we have reconsidered our original Decision in light of Appellants' timely raised points. We withdraw our summary affirmance of the rejection of claims 50–54 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 18, and 25–31 of U.S. Patent No. 7,998,475, but we decline to modify the Decision with regard to any of the obviousness rejections. We address the Appellants' arguments below.

¹ Karl J. Fryxell and Thomas A. Miller, *Autocidal Biological Control: A General Strategy for Insect Control Based on Genetic Transformation with a Highly Conserved Gene*, 88 J. ECONOMIC ENTOMOLOGY 1221–1232 (1995) (“Fryxell”).

² Bruno Bello et al., *Spatial and temporal targeting of gene expression in Drosophila by means of a tetracycline-dependent transactivator system*, 125 DEVELOPMENT 2193–2202 (1998) (“Bello”).

³ Hammock et al., US 5,674,747, issued October 7, 1997 (“Hammock”).

⁴ Stephanie J. Namciu et al., *Human Matrix Attachment Regions Insulate Transgene Expression from Chromosomal Position Effects in Drosophila melanogaster*, 18(4) MOL. AND CELLULAR BIO. 2382–2391 (1998) (“Namciu”).

⁵ Wu-Min Deng, et al., *A targeted gene silencing technique shows that Drosophila myosin VI is required for egg chamber and imaginal disc morphogenesis*, 112 J. CELL SCIENCE 3677–3690 (Oct. 1999) (“Deng”).

DISCUSSION

Nonstatutory Obviousness-type Double Patenting

Appellants argue the Board “committed error when it misapprehended the claims actually on appeal.” Req. Reh’g 3. Appellants argue the Board erred by asserting “that the ODP rejection of claims 50–54 over claims 1, 2, 18, and 25–31 of U.S. Patent No. 7,998,475 B2 was on appeal” because “the Advisory Action mailed June 3, 2013 clearly indicated that the ODP rejection was withdrawn in view of Appellants’ response to the Final Office Action” and the Examiner stated in the Advisory Action that the rejection was “withdrawn in view of Applicant’s arguments.” *Id.* (emphasis original).

Appellants are correct that the nonstatutory obviousness-type rejection of claims 50–54 was withdrawn by the Examiner in the Advisory Action and, therefore, claims 50–54 were not rejected on that basis at the time of the appeal.⁶ Accordingly, we withdraw our affirmance of that rejection. We do not, however, agree that we erred in finding claims 50–54 were on appeal, as the Examiner also rejected claims 50–54 (along with other claims) under 35 U.S.C. § 103 over Fryxell, Bello, and Hammock. Final Act. 6.

Obviousness

The claimed subject matter is directed to a recombinant insect whose genome comprises a dominant lethal genetic system comprising, *inter alia*,

⁶ The Examiner’s provisional rejection on the ground of nonstatutory obviousness-type double patenting over claims 83–88 of copending Application no. 12/278,849 is also moot as that application has been abandoned. Notice of Abandonment, mailed May 9, 2016.

“a lethal gene under the control of a promoter . . . wherein the lethal effect of the system is sex-specific.” *See* Claim 38. Appellants argue the Board erred by misconstruing the claim term “wherein the lethal effect of the system is sex-specific” to encompass the expression of a non-specific lethal gene in only one sex, and, using this construction, in finding that Fryxell disclosed a transgenic insect containing a lethal gene “wherein the lethal effect of the system is sex-specific.” *Req. Reh’g* 4. Appellants argue the Board “failed to consider whether the lethal effect of such gene expression is specific to any single sex” and instead effectively interpreted the term to mean that “the expression or presence of the system is sex-specific.” *Id.* at 4–5.

Appellants argue that the meaning ascribed by the Board is inconsistent with the ordinary and customary meaning of the term, because “‘specificity’ means having the quality of being specific rather than general . . . [and] the lethal effect of the Fryxell system is not specific to any single sex.” *Id.* at 5.

We are not persuaded that we erred in our original Decision. During examination, claims are given their “broadest reasonable construction ‘in light of the specification as it would be interpreted by one of ordinary skill in the art.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005). The claim language specifies that “the lethal *effect* of the system is sex-specific,” but does not otherwise limit the manner by which sex-specificity is achieved for the recombinant insect. Cl. 38 (emphasis added). Accordingly, the broadest reasonable construction of the phrase encompasses a system in which the lethal effect of the gene is felt in only one sex because the gene is expressed only in that sex. As noted previously

(Decision 9), this construction is supported by Appellants' Specification, which describes how the skilled artisan can achieve sex-specific lethality in the claimed transgenic insect:

[E]xpression of the lethal gene or gene product may be controlled so that it is *expressed or produced only in one sex* (or in only one gamete or sexual organ of a hermaphrodite). For example, sex-specific promoters or enhancers may be used, either in combination with sex-specific lethal genes or non-specific lethal genes. Sex-specific splicing provides another mode for sex-specific gene expression. *All possible combinations of non-specific lethal genes, sex-specific lethal genes, non-specific promoters and sex-specific promoters are envisaged by the present invention.*

Spec. 21, ¶ 2 (emphasis added).

As discussed at length in our Decision, the skilled artisan reading the language above would understand the broadest reasonable interpretation of the claim term “wherein the lethal effect of the system is sex-specific” to encompass the expression of a non-specific lethal gene in only one sex, as accomplished by Fryxell with both male-only and female-only populations. Decision at 8–11; FF2–8. In particular, we note that combinations of “non-specific lethal genes” with “non-specific promoters” are contemplated within the scope of the invention. With that particular combination, the skilled artisan would recognize that one manner in which the lethal effect of the system could be sex-specific is to ensure that the non-specific lethal gene along with the non-specific promoter is expressed in only one sex. This is consistent with the disclosure noted by Appellants (i.e., “the original specification discloses that when ‘the sex specific lethal effect of the genetic system [is] manifested’ in a population where both males and females have

the genetic system, only one sex is killed and ‘[a] single sex population remaining may then be isolated’” (Req. Reh’g. 7)), because the skilled artisan would recognize that the Specification describes that the system can *also* use a sex-specific promoter and/or sex-specific lethal gene to trigger lethality of the system. Notably, the claims do not require either a sex-specific gene or a sex-specific promoter.

Appellants acknowledge that the claimed system “may well comprise non-sex specific lethal genes and/or non-sex specific promoters,” but argue:

Nevertheless, the lethal *effect* of the system must still be sex-specific as recited in the claims (*e.g.*, by sex-specific splicing of the non-sex specific lethal genes).” Interpretation of the sex-specific lethal effect must be consistent with the original specification. . . . One of ordinary skill in the art would understand the difference between sex-specific “presence” (or “expression,” using the Board’s terminology) and sex-specific “lethal effect” of the system as recited in the claims. The recited sex-specific “lethal effect” requires more than simple “presence” or “expression” of the system.

Req. Reh’g. 8.

Appellants’ argument is not persuasive, as the record does not support Appellants’ attorney argument that a skilled artisan would understand that “sex-specific splicing of the non-sex specific lethal genes” is the only mechanism by which the combination of non-sex specific lethal genes and non-sex specific promoters may be used in accordance with the invention. The word “splicing” occurs once in the Specification at page 21 ¶ 2 as quoted above: “Sex-specific splicing provides another mode for sex-specific gene expression.” Although that language suggests that the technique of sex-specific splicing may be used, such as to splice a gene into an insect

genome so that the gene would be driven by an endogenous sex-specific promoter, this disclosure does not teach use of splicing with non-sex specific lethal genes and/or non-sex specific promoters, or mandate that when non sex-specific genes and promoters are used, splicing must be necessarily used in order to achieve a sex-specific “effect.” Appellants offer only attorney argument regarding the restrictive meaning they posit that an ordinary artisan would have ascribed to the claim term at issue. We do not find the argument persuasive in light of the teachings of the Specification discussed above.

Appellants further argue that the Examiner’s proposed replacement of Fryxell’s temperature-sensitive lethal gene system with the tetracycline lethal gene system taught by Bello “directly contradicted blackletter law that the proposed modification cannot change the principle of operation of a reference to make a prima facie case.” Req. Reh’g. 11. Although the Examiner found that this feature was met by Fryxell by at least the Final Action dated January 7, 2013, Appellants have not raised this issue before their Request for Rehearing. The Board will not consider a new argument that is “not raised in the appeal brief, or is not responsive to an argument raised in the examiner’s answer . . . unless good cause is shown.” 37 CFR 41.41(b)(2). Appellants have not explained why they waited until this Request for Rehearing to raise this issue, nor do they present sufficient persuasive evidence regarding why a lethal gene triggered by the presence of tetracycline in the organism’s food cannot be successfully substituted for a lethal gene triggered by temperature, as the Examiner has proposed.

Consequently, we shall not consider this new attorney argument, presented without evidence.

Appellants have not persuasively explained how their proposed claim construction of the term “wherein the lethal effect of the system is sex-specific” reconciles with the full scope of the disclosure regarding the manner in which sex-specific lethality may be achieved. Accordingly, we decline to construe the term in the limited manner Appellants request, and we decline to modify our Decision in regards to any of the obviousness rejections in light of the teachings of the prior art.

SUMMARY

We withdraw our summary affirmance of the rejection of claims 50–54 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 18, and 25–31 of U.S. Patent No. 7,998,475.

We maintain the rejections under 35 U.S.C. § 103(a) based on our findings that a preponderance of the evidence supports the Examiner’s conclusion that the combination of Fryxell, Bello, and Hammock discloses the claimed recombinant insect with a dominant lethal genetic system, therefore rendering the appealed claims obvious.

GRANTED-IN-PART; DENIED-IN-PART